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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/772,598	01/30/2001	Timothy E. Benson	6315.N	2967

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MUETING, RAASCH & GEBHARDT, P.A.
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EXAMINER

MAHATAN, CHANNING

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 09/23/2003

14

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/772,598

Applicant(s)

BENSON ET AL.

Examiner

Channing S. Mahatan

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 July 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 35 and 38-43 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 39-43 is/are allowed.
- 6) ☒ Claim(s) 35 and 38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1631

DETAILED ACTION

APPLICANTS' ARGUMENTS

Applicants' arguments in Paper No. 13, filed 08 July 2003, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

CLAIMS UNDER EXAMINATION

Claims herein under examination are claims 35 and 38-43.

Claims Rejected Under 35 U.S.C. § 103

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 38 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Kunsch et al. (Pub. No. US 2003/0054436) taken in view of Rizzi et al. (Proteins: Structure, Function, and Genetics. 1996, Volume 26, pages 236-238) or Sambrook et al. (Molecular Cloning: A Laboratory Manual) or Worthington (Worthington Enzyme Manual: enzymes and related biochemical).

Kunsch et al. discloses isolated *Staphylococcus aureus* polynucleotides and recombinant methods of producing the encoded proteins. (See pages 3-4; Summary of the Invention Section.) Table 2 at pages 42-43 discloses Contig ID Nos. 1192 and 32, as being *Staphylococcus aureus*

Art Unit: 1631

homologs of NAD synthetase. Additionally, the reference teaches on page 10, paragraph [0144] that the proteins can be isolated by freeze-thaw cycling of microbial cells used for recombinant production, thus, resulting in a crystal of the protein. Note that claim 38 does not require any particular type or quality of crystal and that the claim is not limited to a particular sequence.

Rizzi et al. or Sambrook et al. or Worthington discloses routine procedures for protein purification (i.e. NAD synthetase, fusion protein, enzymes, etc) and storage (i.e. -20°C) thereafter (Rizzi et al.: pages 236-237; Sambrook et al.: page 17.30; and Worthington: section XIV, right column).

Therefore, one of ordinary skill in the art would recognize that the utilization of recombinant techniques for the isolation/production of *Staphylococcus aureus* polypeptides (i.e. nicotinamide adenine dinucleotide) would at minimum result in a crystal (i.e. frozen for storage). Applicants claim is not limited to “a crystalline form of protein P having unit cell dimensions” and are therefore read broadly to encompass a protein in crystalline form (i.e. frozen, ice form, etc).

The rejection of claim 35 under 35 U.S.C. § 103(a) as being unpatentable over Crystal Screen™ (Hampton Research) taken in view of Kunsch et al. (Pub. No. US 2003/0054436) is maintained.

Again it is reiterated that Crystal Screen™ is a complete reagent kit designed to provide rapid a screening method for the crystallization of biological molecules (i.e. proteins, etc) and allows for the determination of crystallization conditions (page 1, Column 1, lines 1-4). Absent from the instant claim (i.e. claim 35) are specific “final crystallization conditions” that would allow one to distinguish a preliminary crystal from a specific final crystal.

Art Unit: 1631

Kunsch et al. discloses isolated *Staphylococcus aureus* polynucleotides and recombinant methods of producing the encoded proteins. (See pages 3-4; Summary of the Invention Section.) Table 2 at pages 42-43 discloses Contig ID Nos. 1192 and 32, as being *Staphylococcus aureus* homologs of NAD synthetase.

Thus, it would have been obvious to someone of ordinary skill in the art at the time of the invention to practice Crystal Screen™, determination of crystallization conditions for a biological molecule (i.e. protein) and obtaining a crystal of a biological molecule with Kunsch et al. (Pub. No. US 2003/0054436) *Staphylococcus aureus* NAD synthetase for further study and characterization of the protein and potential binding agents (i.e. drugs) (Kunsch et al. page 16, Screening Assay for Binding Agents section). Crystal Screen™ is also effective in determining the solubility of a molecule in a wide range of precipitants and pH (page 1, Column 1, lines 4-5).

Applicants' arguments that: 1) fails to teach or suggest all of the claim language; 2) Kunsch et al. fails to teach crystals of *Staphylococcus aureus* nicotinamide adenine dinucleotide or methods of crystallizing *Staphylococcus aureus* nicotinamide adenine dinucleotide; 3) Crystal Screen™ reagent kit provides no teaching or suggestion that *Staphylococcus aureus* nicotinamide adenine dinucleotide can be crystallized using the reagent kit; and 4) cites the following from Case 4, Trilateral Project WM4 on Comparative study on "protein 3-dimensional (3-D) structure related claims":

With respect to novelty, it is recognized in the art that a crystal of protein P is different from previously known forms of protein P. Furthermore, the claim complies with the nonobviousness requirement of 35 U.S.C. 103 because as noted in the fact pattern, there was no prior art reference teaching or suggesting a crystal of protein P or related proteins.

are found unpersuasive as addressed above as discussed above. With regard to Applicants' citation of Case 4, Trilateral Project WM4 on Comparative study on "protein 3-dimensional (3-

Art Unit: 1631

D) structure related claims" the instant claims fail to recite structurally the hypothetical claim ("A crystalline form of protein P having unit cell dimensions of $a = 4.0\text{nm}$, $b = 7.8\text{nm}$, and $c = 11.0\text{nm}$).

ALLOWABLE CLAIMS

Claims 39-43 are found allowable.

EXAMINER INFORMATION

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 C.F.R. § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242 or (703) 305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Channing S. Mahatan whose telephone number is (703) 308-2380. The examiner can normally be reached on M-F (8:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward, Ph.D., can be reached on (703) 308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instruments Examiner, Tina M. Plunkett, whose telephone number is (703) 305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

Date: *September 22, 2003*

Examiner Initials: *CSM*

Marianne P. Allen
MARIANNE P. ALLEN
PRIMARY EXAMINER
GROUP 1800
AU1631